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21839 7590 03/26/2009

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ALEXANDRIA, VA 22313-1404

EXAMINER

MARCETICH, ADAM M

ART UNIT

PAPER NUMBER

3761

DATE MAILED: 03/26/2009

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/574,201

03/31/2006

Hiroyuki Sugawara

1034509-000002

8956

TITLE OF INVENTION: METHOD OF PRODUCING BLOOD PROCESSING CIRCUITS AND FILTER UNIT

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	\$1510	\$300	\$0	\$1810	06/26/2009

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

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**Complete and send this form, together with applicable fee(s), to: Mail Mail Stop ISSUE FEE
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INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

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21839 7590 03/26/2009

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I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/574,201	03/31/2006	Hiroyuki Sugawara	1034509-000002	8956

TITLE OF INVENTION: METHOD OF PRODUCING BLOOD PROCESSING CIRCUITS AND FILTER UNIT

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	\$1510	\$300	\$0	\$1810	06/26/2009

EXAMINER	ART UNIT	CLASS-SUBCLASS
MARCETICH, ADAM M	3761	604-006090

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

- ☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.
- ☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list

- (1) the names of up to 3 registered patent attorneys or agents OR, alternatively, 1 _____
- (2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed. 2 _____
- 3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) : ☐ Individual ☐ Corporation or other private group entity ☐ Government

4a. The following fee(s) are submitted:

- ☐ Issue Fee
- ☐ Publication Fee (No small entity discount permitted)
- ☐ Advance Order - # of Copies _____

4b. Payment of Fee(s); (Please first reapply any previously paid issue fee shown above)

- ☐ A check is enclosed.
- ☐ Payment by credit card. Form PTO-2038 is attached.
- ☐ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

5. Change in Entity Status (from status indicated above)

- ☐ a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27. ☐ b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2).

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

Authorized Signature _____

Date _____

Typed or printed name _____

Registration No. _____

This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

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10/574,201	03/31/2006	Hiroyuki Sugawara	1034509-000002	8956
21839	7590	03/26/2009	EXAMINER	
BUCHANAN, INGERSOLL & ROONEY PC POST OFFICE BOX 1404 ALEXANDRIA, VA 22313-1404			MARCETICH, ADAM M	
			ART UNIT	PAPER NUMBER
			3761	
DATE MAILED: 03/26/2009				

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b) (application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 0 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 0 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (<http://pair.uspto.gov>).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

Notice of Allowability	Application No.	Applicant(s)	
	10/574,201	SUGAWARA, HIROYUKI	
	Examiner	Art Unit	
	Adam Marcetich	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 18 December 2008.
2. ☒ The allowed claim(s) is/are 3,4,7-13,15,16,20,26-30 and 34-42.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☒ All b) ☐ Some* c) ☐ None of the:
 1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
 - * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____. |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date _____ | 7. <input type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____. |

/Adam Marcetich/
Examiner, Art Unit 3761

DETAILED ACTION

Priority

1. Acknowledgment is made of Applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy of Japan 2003-344752, filed on 02 October 2003 has been filed.

ALLOWABLE CLAIMS

2. Claims 3,4,7-13,15,16,20,26-30 and 34-42 are allowed over the prior art of record.

REASONS FOR ALLOWANCE

3. The following is an Examiner's statement of reasons for allowance:
4. The closest prior art of record, Johnson et al. (US Patent 5,180,504), discloses the limitations of:

a primary bag (column 4, lines 13-24 and Fig. 6, primary bag 16);
a secondary bag (column 7, lines 15-22 and Fig. 6, transfer bag 34);
a filter unit comprising an inlet and an outlet (Fig. 6, filtration device 40 having upper and lower ends); and
tubing made from PVC (column 4, lines 42-46), a plastic capable of being cut, melted and aseptically connected. However, Johnson fails to teach or fairly suggest alone or in combination the essential steps of the claimed method and device, such as

cutting a second tube, both ends of which are connected to said inlet and said outlet, and to which a bag is not connected. This limitation appears in claims 3 and 4 of the amended claims filed 25 June 2008. Additionally, Johnson lacks a step of cutting a second tube (attached to the filter) so that the second tube comprises first and second cut ends. This step is critical since it allows a filter unit 14 to be sterilized using a different method than applied to a connected bag set 1 (specification p. 22, lines 12-21). Additionally, this configuration of a second tube in a closed cyclic circuit allows the inside of a filter to remain sterile without additional packaging, thus reducing costs.

This step of cutting a “second tube, both ends of which are connected to said inlet and said outlet, and to which a bag is not connected” is supported in the immediate specification (p. 20, lines 15-19; p. 21-22, lines 22-2 and Figs. 1, 2, tubes 5 and 16 connected at marks A1, A2, B1 and B2).

5. Similarly, Fell (US Patent 6,733,433) discloses the limitations of:

a primary bag (col. 6, lines 60-66, Fig. 3, bag 40);

a plurality of secondary bags (column 6, lines 66-67 through column 7, lines 1-2, column 8, lines 59-63 and Fig. 3, bags 42-44 respectively); and

a filter (column 6, lines 60-66 and Fig. 3, bacterial filter 54). However, Fell lacks the critical step of cutting a second tube attached to a filter as claimed [claims 3 and 4]. Additionally, bacterial filter 54 as taught by Fell is not disclosed as performing leukoreduction or leukofiltration.

6. Also important to note, Kuroda et al. (US Patent 4,985,153) discloses the limitations of:

a primary bag and a plurality of secondary bags (col. 3, lines 38-47, Fig. 2, blood collector means 1 and satellite bags 4 and 5);

a filter (col. 3, lines 38-42, Fig. 1, Figs. 1-2, filter means 2); and

cutting a conduit connecting bags (col. 4, lines 34-41). Kuroda further discloses tubing made of PVC, which is adaptable for sterile cutting and hermetic sealing (col. 15, lines 49-61). However, Kuroda lacks the critical step of cutting a second tube attached to a filter as claimed [claims 3 and 4]. Additionally, Kuroda discloses the system as being sterilized in a single step, which teaches away from the advantage of sterilizing a filter using a separate method from that used to sterilize other components (col. 16, lines 1-16, unit sterilized entirely).

7. Examiner also notes that Goldhaber et al. (US Patent 5,269,946) discloses the limitations of:

a primary bag and secondary bag (col. 4, lines 64-68, Figs. 1-4, primary bag 16 and container / transfer bag 34);

a filter (col. 5, lines 30-37, Figs. 1-4, separation device 40); and

hermetically cutting and sealing tubing components connecting bags (col. 8, lines 34-46, especially lines 39-44, Fig. 6, devices 66a-66d). However, Goldhaber lacks the critical step of cutting a second tube attached to a filter as claimed [claims 3 and 4], since separation device 40 is disclosed as being initially attached to a bag (cols. 7-8, lines 62-4, especially lines 1-4, Fig. 6, subassembly 64 comprising separation device 40 connected to transfer bag 34).

8. Lastly, Corbin et al. (US Patent Application Publication No. 2003/0146170)

discloses the limitations of:

a primary bag and a plurality of secondary bags (§ [0065], Fig. 3, blood collection bag 5 and blood product satellite bags 61-64);

a filter (§ [0065], Fig. 3, leukocyte removal filter 26); and

hermetically cutting and sealing tubing components connecting bags (§ [0033], splicing tubes using sterile docking methods). Corbin further discloses filtering blood through a bag and filter set not connected to other bags (§ [0029], [0032]). However, Corbin lacks the critical step of cutting a second tube attached to a filter as claimed [claims 3 and 4], since this filter is disclosed as already attached to a bag.

9. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Response to Amendment

10. Rejections of claims 15, 16, 20, and 26-30 under 35 USC § 112 applied in the Office Action dated 18 September 2008 are withdrawn in view of the amendments filed 18 December 2008.

11. Applicant has amended claim 20 as a “blood treatment circuit,” which resolves the ambiguity between a filter connected to a tubing loop with *both* ends connected to the filter inlet and outlet versus a filter connected to a bag set with multiple tubing ends. Presently, claim 20 calls for a blood treatment circuit in an assembled state. The blood treatment circuit of claim 20 now clearly claims an assembled circuit comprising a filter which was previously connected to a tubing loop with both ends connected to the filter inlet and outlet.

12. Applicant has introduced new claims 34-42, which claim a blood treatment circuit assembled by steps similar to those in independent claims 3, 4 and 20.

13. New claim 35 recites a second tube having a mark indicating the position of its connection to said first tube or said third tube. New claim 37 recites the mark indicating correct connection. Both of these limitations are supported by Fig. 1.

14. New claims 39 and 40 recite a connected bag set that is a moist heat sterilized connected bag set, and a filter unit that is not a moist heat sterilized filter unit. Similar limitations appear in previously presented claims 12 and 13 and are supported by the specification.

15. New claims 41 and 42 recite a connected bag set that is a moist heat sterilized connected bag set, and a filter unit that is a gas sterilized filter unit or a radiation

Art Unit: 3761

sterilized filter unit. Similar limitations appear in previously presented claim 13 and are supported by the specification.

16. Examiner acknowledges amendments to claim 28 for minor formalities filed 02 February 2009.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Adam Marcetich whose telephone number is 571-272-2590. The examiner can normally be reached on 8:00am to 4:00pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Adam Marcetich/
Examiner, Art Unit 3761

/Leslie R. Deak/
Primary Examiner, Art Unit 3761
12 March 2009